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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 08/460,715 | 06/02/1995 | MICHAEL MACH | 5552.0738-02 | 5690 |

22852 7590 10/06/2003

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| EXAMINER |
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WORTMAN, DONNA C

| ART UNIT | PAPER NUMBER |
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1648

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DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

08/460,715

Applicant(s)

MACH ET AL.

Examiner

Donna C. Wortman, Ph.D.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 10 September 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): please see attached.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: 37, 39, 62, 63, 73, 7, 74, 41-43, 45-47, 64-66, 87, 75, 80, 76, 48-52, 67-69, 82, 83, 58-60, and 70-72.

Claim(s) objected to: _____

Claim(s) rejected: 8, 55-57, 77-79, 81 and 84-86.

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____


Donna C. Wortman, Ph.D.
Primary Examiner
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Claims 37, 39, 62 and 63 were previously indicated allowable.

In the after final amendment, claims 7, 49, 73-76, 81-83, and 85 were amended and new claim 87 was added.

Applicant's amendment after final submitted 10 September 2003 has been entered. As a result, the objection to claims 81 and 85, and the rejection of claims 73, 77-79, 74, 41-43, 45-47, 64-66, 75, 80, 81, 76, 48-52, 67-69, 82, 84-86, 83, 55-60, and 70-72 under 35 USC 112, second paragraph, are withdrawn.

Claim 73 is directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 7 and 8, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claims 7 and 8 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made in Paper No. 9 is hereby withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 8 is confusing because it depends from claim 7, which recites "...expression vector which encodes for said entire HCMV pp28 ...", but recites "wherein the 1.0 kB SmaI fragment ... or fragments equivalent thereto ... are used." It is not understood how the 1.0 kB SmaI fragment, or other fragments, can encode the entire HCMV pp28.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No support could be found for use of fragments equivalent to the 1.0 kB SmaI fragment from the HindIII R fragment from other HCMV strains.

Claims 77-79, 81, 84-86, and 55-57 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record in Paper No. 37.

Applicant has pointed to various locations in the specification that disclose vector and cell types for expression of antigenic portions of pp28 and has pointed out that prokaryotic cells and vectors are broadly disclosed and has argued that one of skill in the art would understand that the same combinations of cell syptes and vectors could be used to express the entire pp28. Applicant has also pointed out the disclosure of the

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use of human fibroblast cells and has argued that eukaryotic cells are broadly disclosed and that the same cell types and vectors could be used to express the entire pp28.

This argument has been considered but not found persuasive, since the issue is not one of enablement, i.e., whether one would know how to practice the invention as claimed, but one of written description, i.e., whether or not the invention is described in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification does not describe the use of any particular prokaryotic vectors or cell types to express the entire pp28, and does not describe the use of any particular eukaryotic cell types to express either an antigenic portion or the entire pp28. The only mention of human fibroblasts is in the context of an HCMV-infected cultured cells.

Claims 37, 39, 62, 63, 73, 74, 41-43, 45-47, 64-66, 87, 75, 80, 76, 48-52, 67-69, 82, 83, 58-60, and 70-72 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'D. Wortman', with a stylized flourish at the end.

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw